K010065

JUL - 2 2002

play medical

radiothérapie
radiotherapy
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curiethérapie
brachytherapy
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radioprotection

Premarket Notification [510(k)] Summary
Tab 4

December 22, 2000

Trade Name: Cranial Stereotactic Equipment

Common Name: Linear Accelerator Stereotactic Hardware

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: BrainLAB Linac Hardware, K934657

Device Description: The Cranial Stereotactic Equipment system provides the equipment necessary to enable any standard model linear accelerator to perform cranial stereotactic radiosurgery and stereotactic radiation therapy (SRS/SRT). Arplay Medical S.A. markets this device outside of the United States and now submitting for a clearance to market it within the U.S.

The Cranial Stereotactic Equipment system consists of a collimator mount, customized to attach to a specific manufacturers model of medical linear accelerator, a selection of collimators, and couch mount, customized to attach to a specific manufacturers model of patient treatment couch. These components are listed below.

Components of the Cranial Stereotactic Equipment system

1. Collimator Mount
2. Collimators: straight or focused, 5mm to 50 mm treatment field at 100 cm.
3. Couch Mount
4. Phantom Pointer
5. Film Holder

The customer specifies the make and model of medical linear accelerator, the collimator diameters required, the make and model of the patient treatment couch and the make and model of the stereotactic head frame that will be used. Arplay supplies the correct mounts and collimators requested.

Prior to a patient treatment, the Collimator mount is attached to the linac treatment mount and the couch mount is attached to the treatment couch. The prescribed collimator is fixed to the collimator mount. The head frame is attached to the patient in accordance with the head frame manufacturers' directions. (The head frame is not an Arplay device).

To confirm the proper alignment of these devices, a quality assurance check is made. The Film Holder is attached to the collimator mount and the Phantom Pointer with the selected tip is attached to the couch mount. When the alignment is correct, the patient treatment can begin.

Intended Use: The Cranial Stereotactic Equipment system provides the equipment necessary to enable any standard model linear accelerator to perform cranial stereotactic radiosurgery and stereotactic radiation therapy (SRS/SRT).

Technological Characteristics: See the attached Predicate Comparison Table

#	Feature	BrainLAB Linac Hardware, K934657	Arplay Medical Cranial Stereotactic Equipment
1	Collimator Mount	Yes, Available for all Linacs	Yes, Available for all Linacs
2	Interchangeable Collimators	5 mm to 50 mm dia. At 100 cm SAD, Straight and Focused	5 mm to 50 mm dia. At 100 cm SAD, Straight and Focused
3	Couch Mount	Yes, available for all couches	Yes, available for all couches
4	QA Tool, Phantom Pointer	Yes	Yes
5	QA tool, Film Holder	Yes	Yes

The Arplay Medical Cranial Stereotactic Equipment system has the same intended use and safety characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Richard Borgi, M.D.
President & CEO
ARPLAY Medical SAS
Capital 1.110.000 €
1, Route de Citeaux
21110 IZEURE-FRANCE

Re: K010065
Trade/Device Name: Cranial Stereotactic Equipment
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: June 29, 2001
Received: April 12, 2002

Dear Dr. Borgi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K010065

Device Name: Cranial Stereotactic Equipment

Indications for Use:
To enable any standard model linear accelerator to perform cranial stereotactic radiosurgery and stereotactic radiation therapy (SRS/SRT).

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010065